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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,248	12/04/2003	Paul Dicarlo	01194-824001	7802
26161 7590 09/04/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER TOWA, RENE T	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 09/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/728,248

Applicant(s)

DICARLO ET AL.

Examiner

Rene Towa

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The last Office action, dated June 1, 2007, is vacated. This Office action treats the pending claims on the merit.
2. This Office action is responsive to an amendment filed March 14, 2007. Claims 1-33 are pending. Claim 15 has been amended. No claim has been cancelled. New claims 22-33 have been added.

Election/Restrictions

3. The restriction is withdrawn due to Applicant's Remarks essentially indicating that Applicant's introduction of new claims 22-33 are a product of a previous Examiner's suggestion of allowable subject matter, which subject matter was later rejected in the Office action, dated December 15, 2006, upon discovery of a new prior art by the instant Examiner.

Claim Objections

4. The objections are withdrawn due to amendments.

Claim Rejections - 35 USC § 102

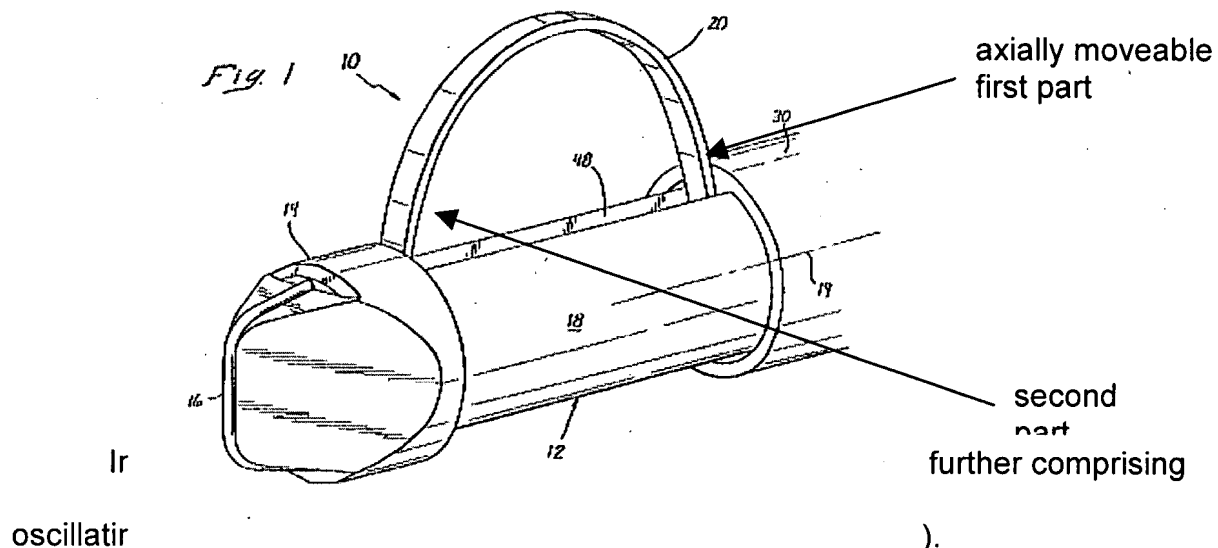
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 15-16 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al. (US Patent No. 6,331,166).

In regards to claim 15, Burbank et al. discloses a method of using a medical instrument, the method comprising:

moving a stylet 18 and a stylet block 20 from a first position to a second position, the stylet block 20 having an axially moveable first part and a second part attached to the stylet 18, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet 18;

simultaneously causing rotation of the stylet 18 along an axis of the stylet 18 by engagement between second part of the stylet block 20 and a housing of the medical instrument; and

moving a cannula 30 over the stylet 18 (see fig. 1; column 4/lines 48-60; column 5/lines 38-42 & 44-49; column 7/lines 11-25 & 39-46).



In regards to claim 20, Burbank et al. discloses a method comprising rotating the stylet 18 in one direction (see column 7/lines 11-24).

In regards to claim 21, Burbank et al. discloses a method comprising rotating in multiple directions (see column 7/lines 11-24).

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. **Claims 1-11 & 23-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. (US Patent No. 5,368,045) in view of Kornberg et al. (US Patent No. 5,197,484).

In regards to **claim 1**, Clement et al. discloses a medical instrument, comprising:
a housing 8 having a proximal end 10 and a distal end 16;
a stylet 18 having a portion in the housing, the stylet 18 being movable between a first extended position and a first retracted position; and
a cannula 20 coaxially receiving the stylet 18 and having a portion in the housing 8, the cannula 20 being movable between a second extended position and a second retracted position (see figs. 1-2, 3a-d & 4a-4d; column 3/lines 4-16 & 22-32).

In regards to **claim 2**, Clement et al. discloses a medical instrument further comprising a stylet block 36 attached to a proximal end of the stylet 18 and mounted inside the housing 8 (see fig. 2).

In regards to **claims 3 & 22**, Clement et al. discloses a medical instrument wherein the stylet block 36 comprises:

a first part inside the housing 8, the first part being moveable between an extended position and a retracted position (see fig. 2).

Art Unit: 3736

In regards to **claims 9 & 28**, Clement et al. discloses a medical instrument further comprising:

a stylet spring 44 capable of moving the stylet 18 from the first retracted position to the first extended position; and

a cannula spring 40 capable of moving the cannula 20 from the second retracted position to the second extended position (see fig. 2).

In regards to **claims 10 & 29**, Clement et al. discloses a medical instrument further comprising:

a first pivoting latch 52 capable of retaining the stylet 18 in a predetermined position when the stylet 18 is in the first retracted position; and

a second pivoting latch 60 capable of retaining the cannula 20 in a predetermined position when the cannula is in the second retracted position (see fig. 2).

In regards to **claims 11 & 30**, Clement et al. discloses a medical instrument wherein the stylet 18 comprises a notch 30 with a sharpened leading edge (see fig. 1c).

Clement et al. disclose an instrument, as described above, that fails to teach a stylet configured to rotate when moved from the first retracted position to the first extended position.

However, with respect to **claims 4-8 & 23-27**, Kornberg et al. disclose an instrument including a part 91 attached to a proximal end of a cannula 54, the part 91 being rotatably engaged with a first part and being able to rotate relative to an axis of the cannula 54;

Art Unit: 3736

wherein the housing 70 comprises a semi-cylindrical portion defining a track 158 configured to engage with the second part 91;

wherein the second part 91 comprises:

a projection 94 in contact with a track 158 associated with the housing 70, the projection 94 and track 158 capable of cooperating to axially rotate the second part 91 and the attached cannula 54 when the cannula 54 is moved between the first extended position and the first retracted position; wherein the track 158 is molded into the interior side of the housing 70;

wherein the track 158 is configured to provide unidirectional rotation to the cannula 54; wherein the track is configured to provide multidirectional rotation to the cannula 54 (see figs. 9, 12, 17 & 28; column 2/lines 1-9; column 3/lines 39-50 & 52-66; column 4/lines 29-31, 39-42 & 49-61; column 8/lines 18-23 & 25-32; column 9/lines 25-40 & 53-61; column 10/lines 3-6 & 19-24; column 11/lines 27-34 & 46-53; column 12/lines 2-5, 25-32 & 40-47; column 13/lines 19-25; column 14/lines 26-34 & 45-47).

Applying the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Because both Clement et al. and Kornberg et al. teach biopsy instruments and since Kornberg et al. further teach a driving mechanism for simultaneously rotating and

Art Unit: 3736

forwardly driving a cannula into body tissues, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an instrument similar to that of Clement et al. with a simultaneously rotating and forwardly driven stylet mechanism similar to that of Kornberg et al. in order to automatically rotate the stylet as it penetrates tissue so as to facilitate tissue penetration.

9. **Claims 12, 14, 31 & 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484) further in view of Kass (US Patent No. 5,921,943).

Clement et al. as modified by Kornberg et al. disclose an instrument, as described above that teaches all the limitations of the claims except Clement et al. as modified by Kornberg et al. do not teach two openings and an opening opposing the notch. However, Kass discloses an instrument comprising a stylet including two openings for a notch, which can also be viewed as a notch and an opening opposing the notch (which can be seen in Figure 19) for receiving tissue that has been cut by cutting cannula (see Column 9, lines 15-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Haaga with a notch having two openings and an opening opposing the notch, as taught by Kass, for receiving tissue that has been cut by cutting cannula.

10. **Claims 13 & 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. ('045) in view of Kornberg et al. ('484) further in view of Haaga (US Patent No. 5,394,887).

Clement et al. as modified by Kornberg et al. disclose an instrument, as described above that teaches all the limitations of the claims except Clement et al. as modified by Kornberg et al. do not teach a notch comprising a ramped surface.

However, Haaga teaches it is known to provide a stylet with notch having a ramped surface (see Figure 3 around elements 38 and 40), to secure the stylet in the tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch (see Column 2, lines 52-55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Clement et al. as modified by Kornberg et al. with a stylet having a notch with a ramped surface, as taught by Haaga to secure the stylet in the tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch.

11. **Claims 17-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al. ('166) in view of Ritchart et al. (US Patent No. 5,649,547).

Burbank et al. disclose a method, as described above, that teaches all the limitations of the claims except Burbank et al. do not teach the step of collecting a sample in a notch of the stylet. However, Ritchart et al. disclose a method comprising the step of collecting a sample in a notch 28 of a stylet; wherein the method further comprises removing the sample from the notch 28 by inserting an object 22 through an opening located in the notch 28 (see figs. 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method

Art Unit: 3736

similar to that of Burbank et al. with a method step comprising removing the tissue through a notch similar to that of Ritchart et al. in order to conveniently collect the severed tissues (see Burbank et al., column 8/lines 39-46).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Burbank et al. as modified by Ritchart et al. with a step of removing the sample over an inclined surface since such a modification would amount to a design choice that would serve the same purpose of removing the severed tissue. Even moreover yet, the Applicant has not disclosed that removing the tissue over an inclined surface provides an advantage, is used for a particular purpose, or solves a stated problem.

Response to Arguments

12. Applicant's arguments filed March 14, 2007 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RTT/

Matthew H. E. [Signature]
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